

AUG - 4 2003

2. 510(K) SUMMARY

K023548

2.1 *Administrative Information*

2.1.1 Name and address

Submitted by: Velocimed Inc
11400 73rd Avenue North, Suite 134
Minneapolis, MN 55369

Contact Person: John Carline
Telephone No.: 763-463-4742
Facsimile No.: 763-488-9780

Date Prepared: October 21, 2002

2.1.2 Device Name

Trade Name	Proxis Flow-Control Device
Common Name	Occlusion Balloon Catheter, Infusion Catheter
Classification Name	Catheter, Intravascular Occluding, Temporary Intravascular Diagnostic
Classification	Class II MJN, DQY

2.1.3 Applicant

Applicant's Name: Velocimed Inc
11400 73rd Avenue North, Suite 134
Minneapolis, MN 55369

2.2 *Predicate Devices*

The Proxis Flow-Control Device is substantially equivalent to the Equinox Occlusion Balloon Catheter (K 990487), 4.5F ImageCath Coronary Angioscope (K952638), Dispatch Coronary Infusion Catheter (K932616), and the Isolate Infusion Catheter (K913517).

2.3 *Indication for use*

The Proxis Flow-Control device controls the flow of fluids in the coronary and periphery vasculature. This is achieved by the temporary occlusion of vessels and

holding the column of fluid in the vessel stagnant. The stagnant column can be used to aid in the visualization of the lesion or be used as a means of local and temporary delivery of therapeutic solution(s). The safety and efficacy of this device as an embolic protection system has not been established. The Proxis Flow Control device is not indicated for use for embolic protection.

2.4 Device Description

The Proxis Flow-Control device is a dual balloon catheter. It has four major components: The Evacuation Sheath Catheter, the Inflation System, Infusion Catheter System, and an Evacuation syringe.

The Evacuation Sheath also has two low-pressure compliant balloons that are inflated simultaneously. The proximal balloon stays within the guide catheter while the distal balloon resides in the arterial vessel. Radiopaque markers at the two balloon sites facilitate visualization and intravascular placement of the catheter prior to inflation. The Evacuation Sheath has an inner diameter of 0.058 inches and can accommodate standard therapeutic devices that have profiles of 0.058 inches or lower. The balloons are inflated using the Inflation System.

Devices can be deployed through the Evacuation sheath to the target site before, during or after the Proxis balloons are inflated, and the vessel occluded. Infusing less than 0.5cc of contrast dye through the guide catheter will produce a "roadmap" of the lesion as an aid for the physician in guiding the therapeutic device to the lesion site.

Alternatively, less than 0.5cc of therapeutic solutions like anticoagulant, cardioplegia and thrombolytics may be infused through the guide catheter and stagnated in the target vessel/lesion during the delivery of the therapeutic device or after the deployment of the therapeutic device while the vessel is occluded.

The Evacuation syringe is provided in the event that removal of contrast, or therapeutic solution is desired. If distal perfusion of fluid is needed during evacuation, the Infusion Catheter System may be used.

2.5 Substantial Equivalence

The Proxis Flow-Control device covered by this submission is substantially equivalent to other legally marketed Occlusion Balloon Catheters. Specifically, the Proxis Flow-Control device is substantially equivalent to the Parodi Catheter for Angiography (K 001917), the Equinox Occlusion Balloon Catheter (K 990487), the 4.5F ImageCath Coronary Angioscope (K952638), Dispatch Coronary Infusion Catheter (K932616) and the Isolate Infusion Catheter (K913517). The Proxis has the same general indication for use, similar principles of operation, and similar technological characteristics as the previously cleared predicate devices. The differences between this device and its predicate devices do not raise new questions of safety or efficacy.

2.6 Performance Data

The performance test data is provided in the 510(k) submission. The performance data demonstrates that the device complies with the applicable sections of:

- ISO 10555 (Part 1 and Part 4),
- ISO 10993-1,
- Product specification
- ASTM D-4169 (Packaging Integrity Testing)
- ISO 11607 (Packaging for terminally sterilized medical devices)
- ISO 11135: 1994(E) (Validation and routine control of ETO sterilization)

Performance testing included dimensional verification, balloon compliance and integrity, catheter tensile strength, torque strength, flexibility and trackability. Nine acute and eight chronic animals were used to test and validate the performance and safety of the device. Test results demonstrate that the device meets or exceeds the requirements of these standards and performs substantially equivalent to the predicate devices.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

AUG - 4 2003

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Velocimed, Inc.
c/o John Carline
Sr. RA Associate
11400 73rd Avenue North
Suite 134
Maple Grove, MN 55369

Re: K023548
Trade/Device Name: Proxis Flow-Control Device
Regulation Number: 21 CFR 870.1250
Regulation Name: Percutaneous catheter
Regulatory Class: Class II
Product Code: DQY
Dated: May 13, 2003
Received: May 14, 2003

Dear Mr. Carline:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set

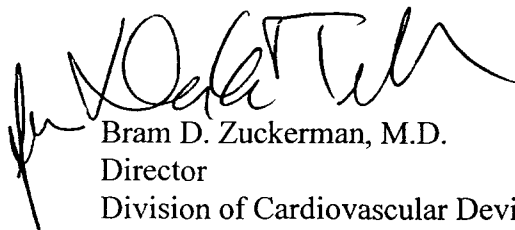
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forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (301) 594-4586. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address <http://www.fda.gov/cdrh/dsma/dsmamain.html>

Sincerely yours,

A handwritten signature in black ink, appearing to read "Bram D. Zuckerman", is written over the typed name and title.

Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

14. INDICATION FOR USE

510(k) Number; K023548

Device Name: Proxis™ Flow-Control

Indication for Use

The Proxis Flow-Control device controls the flow of fluids in the coronary and periphery vasculature. This is achieved by the temporary occlusion of vessels and holding the column of fluid in the vessel stagnant. The stagnant column can be used to aid in the visualization of the lesion or be used as a means of local and temporary delivery of therapeutic solution(s). The safety and efficacy of this device as an embolic protection system has not been established. The Proxis Flow Control device is not indicated for use for embolic protection.

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)


(Division Sign-Off)

Division of Cardiovascular Devices

510(k) Number

K023548

Prescription Use ☒
(Per 21 CFR 801.109)

OR

Over-The Counter Use ☐